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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,438	04/02/2002	Christopher Jeremy Leonard	506-076	1589
7590	12/29/2004		EXAMINER	
Melvin I Stoltz 51 Cherry Street Milford, CT 06460			WARE, DEBORAH K	
			ART UNIT	PAPER NUMBER
			1651	
DATE MAILED: 12/29/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/009,438

Applicant(s)

LEONARD, CHRISTOPHER  
JEREMY

Examiner

Deborah K. Ware

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Newly added claims 13-15 are presented for reconsideration on the merits.

#### ***Amendment***

The amendment filed September 27, 2004, has been received and entered.

Original claims 1-12 have been canceled and claims 13-15 added in place thereof.

#### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 13-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

#### ***Claim Rejections - 35 USC § 112***

Claims 13-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter "that have been fed on a food containing pathogens" in claims 13-14, and "have been fed on a food containing pathogens" in claim 15 does not appear to be supported or described in the instant specification. Therefore, the subject matter appears to be new matter. The

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specification at page 5, lines 1-5, does support growing insects to be used on a substrate inoculated with bacteria or virus when pursuing specific immunological responses; however, preparing a medicament to induce immunity by feeding insects a food containing pathogens such as a biological waste is not clearly described except for when biologically recycling.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 13-15 provide for the use of tissues, larval forms or derivative of insects for preparing a medicament and for use to induce immunity, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13-14 are further rendered vague and indefinite for failing to set forth clear and distinct process steps for how a medicament is actually prepared per se. Also claims 13-14 are rendered vague and indefinite for the term "or derivatives of insects" since it is unclear what a derivative of an insect is per se? The metes and bounds of the claims cannot be determined.

Also the claims are rendered vague and indefinite for the language "the use of tissues" or "derivates of insects" "that have been fed on a food containing pathogens" as recited in claim 13. It is unclear how "tissues" and "derivatives of insects" are fed on a food containing pathogens.

***Claim Rejections - 35 USC § 102/103***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 15 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over EP 1 006 124 A1, cited of record.

Claim is drawn to a medicament prepared using maggots which have been fed on a food containing pathogens.

The EP reference teaches using maggots (*Calliphora vicina* larvae) to prepare a medicament, see page 2, lines 50-57. To prepare a medicament the maggots are fed, see page 4, lines 15-16.

The medicament is identical to the cited disclosure and therefore, the claim is considered to be anticipated by the teachings therein. The medicament of the cited prior art is no different than the claimed medicament. However, in the alternative that there is some unidentified claimed characteristic for which provides for some difference between the two medicament products, then the difference is considered to be so slight as to render the claim prima facie obvious over the cited prior art. Feeding a pathogen or a pathogen containing food to maggots is clearly within the purview of an ordinary artisan. However, the claim is a product claim and the food containing pathogens is not an ingredient of the product per se. Therefore, the claim is considered to be identical to the medicament of the cited disclosure and hence anticipated by therefrom.

***Claim Rejections - 35 USC § 103***

Claims 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP cited reference, noted above in view of newly cited WO 92/00258, cited of record.

Claims are drawn to a method of preparing a medicament to induce immunity in humans, that includes use of insect larvae that have been fed on a food containing pathogens. The food can be a biological waste.

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EP reference teaches feeding larvae to produce a medicament and that larvae produce medicaments, note page 2, lines 50-58 and page 4, lines 15-16.

WO/92 00258 teach feeding biological waste to insect larvae, note the abstract.

The claims differ from EP reference in that biological waste as the food containing pathogens being fed to insect larvae is not disclosed.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to feed the insect larvae capable of producing medicament as disclosed by EP reference the biological waste as disclosed by WO/92 00258. The steps are clearly recognized in the cited prior art that feeding insect larvae to produce a medicament is known and to select for a well known food source such as biological waste as disclosed by the secondary reference is clearly an obvious choice by one of skill in the art. One of skill would have expected successful results especially since the art clearly teaches that insect larvae produce medicaments and do so after being fed (i.e. postfeeding). Hence to select for a food choice such as biological waste would have been prima facie obvious because it is well recognized by the cited prior art to be a useful food for insect larvae. Therefore, in the absence of persuasive evidence to the contrary the claims are rendered prima facie obvious over the cited prior art. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

All claims fail to be patentably distinguishable over the state of the art discussed above. Therefore, the claims are properly rejected.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is 571-272-0924. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



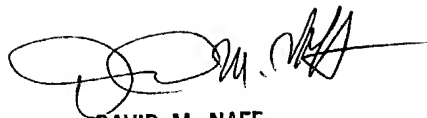
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Deborah K. Ware  
December 23, 2004



DAVID M. NAFF  
PRIMARY EXAMINER  
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